

REMARKS

All the claims submitted for examination in this application has been rejected on formal and/or substantive grounds. Applicants have amended their claims and respectfully submit that all the claims currently in this application are patentable over the rejection of record.

The first ground of rejection is a formal rejection imposed under 35 U.S.C. §112, first paragraph and is directed to Claims 1-4 and 6-15. These claims stand rejected as not being enabled insofar as the generic formula of Claim 1 is exemplified only for the case where n is 2; o is 1; and n is 1. Thus, embodiments of the generic formula where m is 1; o is 2; and n is 2 are not exemplified.

Applicants contest this ground of rejection. This ground of rejection is contrary to the case law. It is well established that the specification need teach only one mode of making and using a claimed product. Johns Hopkins Univ. v. Cellpro, Inc., 152 F.3d 1342, 47 USPQ2d 1705 (Fed. Cir. 1998); Engel Indus. Inc. v. Lockformer Co., 946 F.2d 1528, 20 USPQ2d 1300 (Fed. Cir. 1991).

The second ground of rejection predicated upon lack of enablement, under 35 U.S.C. §112, first paragraph, resides in the rejection of Claims 9, 11, 13 and 15 on the ground that these claims are directed to treating schizophrenia or a disorder or condition which is responsive to the activity of α -7 nicotinic receptor modulators. The Official Action argues that there is no evidence commensurate in scope to that of the rejected claims which demonstrate the effectiveness of the claimed compounds in such treatment. As stated in applicants initial response to this ground of rejection, the literature establishes that α -7 nicotinic receptor agonists are effective in the treatment of schizophrenia and that compounds

within the scope of the formula of Claim 1, from which Claims 9, 11, 13 and 15 each depend, are α -7 nicotine receptor agonists. This evidence, e.g. the teaching in the prior art of the class of compounds having the claimed utility in combination with the specification teaching of the claimed compounds being in the class of compounds having the claimed utility, is enough to establish enablement even in the absence of a showing of this utility. In re Bundy, 642 F.2d 430, 434, 209 USPQ 48, 51-52 (CCPA 1981).

Specifically, the specification of the present application teaches that the compounds of Claim 1 are α -7 nicotinic receptor agonists. The prior art mentioned in the specification indicates that α -7 nicotinic receptor agonists are therapeutic in the treatment of schizophrenia and other central nervous system disorders.

The same argument supports patentability of rejected Claims 12-15 under 35 U.S.C. §112, ¶1. In this regard, applicants submit that even if the Official Action is correct in arguing that the use of α -7 nicotinic acetylcholine receptor agonist in this treatment is speculative, there is no question that the prior art indicates that the use of such agonists in the treatment of central nervous disorders is reasonable since they have been successful in this treatment. As such, the enablement requirement is met.

Claims 1-16 have been rejected, under 35 U.S.C. §112, ¶2, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The first ground of rejection under the indefiniteness requirement is denoted as (d) in the previous Official Action. This ground is predicated upon the alleged indefiniteness of the term “an effective amount of a schizophrenia treating compound of Claim 1” set forth in the claims.

Applicants submit that the test of definitiveness is predicated upon the knowledge by those skilled in the art. The α -7 nicotinic receptor agonizing effective amount of a compound within the scope of the generic formula of Claim 1 is an amount known to those skilled in the art. Obviously, that amount varies from patient to patient but to argue that the subject phrase is indefinite is unsupportable when considered by those skilled in the art.

The rejection, under 35 USC§112, second paragraph, based on indefiniteness predicated upon items (h) to (z) and (aa)-(ac) on the ground that the compounds subject to each of these grounds of rejection have been provisoed out of the generic formula which, applicants assume, the examiner admits is within the scope of the generic formula, is respectfully traversed.

The compounds subject to this ground of rejection all include substituted phenyl compounds. The Official Action conclusion that all compounds which include a phenyl or substituted phenyl group, since the proviso excludes unsubstituted phenyl or phenyl substituted with one or two substituents incorporated in a Markush group of ten members as a meaning of Q when n is 1; o is 1; m is 2; X is oxygen; and Y is oxygen or NR¹, are excluded out of the generic compound of the present application is incorrect. The species rejected as being indefinite were not provisoed out of the scope of the generic formula.

The error in the Official Action analysis resides in the fact that none of the rejected species, albeit they include a substituted phenyl group, meet the other requirements for exclusion of substituted phenyl compounds. That is, none of the rejected compounds of Claim 17 are compounds wherein n is 1; o is 1; m is 2; X is oxygen; and Y is oxygen or NR¹. As such, the rejection based on indefiniteness of items (h) – (z) (aa), (ab) and (ac), is unsustainable.

Claims 17 to 20 have been rejected, for the first time, under 35 U.S.C. §101, as not being supported by a specific utility.

The basis for this ground of rejection relates to the above discussion. That is, Claims 17 to 20 are directed to species which the Official Action avers are compounds specifically provisoed out of the generic formula of Claim 1, from which each of Claims 17 to 20 depend.

Applicants respectfully traverse this ground of rejection for the reasons given above. That is, the compounds recited in Claims 17 to 20 have not been provisoed out of the application insofar as the proviso requires the conditions mentioned above which, applicants submit, is not met by the rejected species which contained substituted phenyl groups.

Nine additional separate grounds of rejection have been imposed in support of the proposition that Claims 1 to 16 are unpatentable, under 35 U.S.C. §112, ¶2, as being indefinite. These grounds of rejection are discussed below.

Item (a) is a rejection of Claim 1 based on the redundant use of the indefinite article “a.” This ground of rejection has been overcome by deleting one of them following “Q is ...”.

Item (b) has been overcome by redrafting the Markush group in Claim 1 to introduce the word “and” between the penultimate and ultimate members of the heteroatom group.

The rejection of Claims 12 to 15, in item (c), based on the inclusion of a close parenthesis after “cocaine” has been made moot by the cancellation of the close parenthesis in each of Claims 12 to 15.

The rejection of Claim 16 is based on the Official Action allegation that the species of items (d) to (i) are not provided with antecedent basis from Claim 1, from which Claim 16 depends. The argument that the compounds focused upon in items (d) to (i) are not properly

dependent from Claim 1, insofar as these species are outside the scope of the compound having the structural formula I in Claim 1, is predicated upon the proviso discussed above. However, applicants again respectfully submit that not only are the compounds subject to the alleged absence of antecedent basis within the scope of the generic formula, but, in addition, the proviso does not apply to these compounds.

Turning now to substantive rejections imposed in the outstanding Official Action, Claim 20 stands rejected, under 35 U.S.C. §102(a), as being anticipated by International Publication WO 00/58311 to Gallet et al.

Applicants respectfully traverse this ground of rejection. The compound of Claim 20, 1,4-diazia-bicyclo[3.2.2]nonane-4-carboxylic acid 4-bromo-phenyl ester, applicants aver, is outside the scope of the generic compound I of Gallet et al.

Attention is directed to structural formula I of Gallet et al which requires that the meaning of Y in the structural formula I of Claim 1 of the present application, from which Claim 20 depends, be a bond, in the case where n is 0, or oxygen, sulfur or NR^1 , where R^1 is hydrogen, $\text{C}_1\text{-C}_8$ alkyl $\text{C}(=\text{O})\text{OR}^6$ or $-\text{C}(=\text{O})\text{NR}^6\text{R}^7$. Suffice it to say, none of these meanings is equivalent to the meaning of alkylene, e.g. $(\text{CH}_2)_n$, where n is 0, 1 or 2, as required by Gallet et al. As such, the compound of Claim 20, which is properly dependent from Claim 1, is not anticipated by Gallet et al.

The second substantive ground of rejection is directed to Claims 16-20. These claims stand rejected, under 35 U.S.C. §103(a), as being unpatentable over Gallet et al. The Official Action avers that the generic formula of Gallet et al. encompasses species of Claims 17 to 20 and the fourth species of Claim 16.

Applicants again traverse this ground of rejection. No compound within the scope of Claims 16 to 20 is encompassed by the generic formula of Gallet et al. for the reason given above in the traverse of the anticipation rejection.

Even if compounds within the scope of Claims 16 to 20 were within the contemplation of the generic formula of Gallet et al., which applicants strongly submit is not the case, still in the absence of similar utility, which is not the case, the generic formula of Gallet et al. would not make obvious any of the compounds within the scope of Claims 16 to 20.

The disclosure of a genus which encompasses a multiplicity of species, including a claimed species, where it would not be obvious to utilize compounds of the genus in the utility of the claimed species does not present a prima facie case of obviousness. In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

It is emphasized that the sole application provided for the compounds within the scope of Gallet et al. are as therapeutics, the exact details of which is not provided in the brief English portion of Gallet et al. In the absence of the proffering of an English translation by the USPTO spelling out what therapeutic action are possessed by compounds within the scope of the Gallet et al., applicants submit that there is no disclosure or suggestion of using compounds within the scope of Gallet et al. in the treatment of schizophrenia or other disorders of the central nervous system.

Reconsideration and removal of the substantive grounds of rejection in view of the above remarks is deemed appropriate. Such action is respectfully urged.

The above amendment and remarks establish the patentable nature of all the claims currently in this application. Notice of Allowance and passage to issue of these claims,

Claims 1-20, is therefore respectfully solicited.

Respectfully submitted,

A handwritten signature in black ink, reading "Marvin Bressler", followed by a long horizontal flourish line.

Marvin Bressler
Registration No. 25,132
Attorney for Applicants

Scully, Scott, Murphy & Presser
400 Garden City Plaza
Garden City, New York 11530
516-742-4343
MB:ml